

PATENT COOPERATION TREATY

Translation

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing
(day/month/year)

Applicant's or agent's file reference

LEA36769-WO

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/EP2004/006682

International filing date (day/month/year)

21.06.2004

Priority date (day/month/year)

02.07.2003

International Patent Classification (IPC) or both national classification and IPC

Applicant

BAYER HEALTHCARE AG

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input checked="" type="checkbox"/> | Box No. II | Priority |
| <input checked="" type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input checked="" type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/EP

Authorized officer

Facsimile No.

Telephone No.

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Box No. I	Basis of this opinion
1.	<p>With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.</p> <p><input type="checkbox"/> This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).</p>
2.	<p>With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:</p> <p>a. type of material</p> <p><input type="checkbox"/> a sequence listing</p> <p><input type="checkbox"/> table(s) related to the sequence listing</p> <p>b. format of material</p> <p><input type="checkbox"/> in written format</p> <p><input type="checkbox"/> in computer readable form</p> <p>c. time of filing/furnishing</p> <p><input type="checkbox"/> contained in the international application as filed.</p> <p><input type="checkbox"/> filed together with the international application in computer readable form.</p> <p><input type="checkbox"/> furnished subsequently to this Authority for the purposes of search.</p>
3.	<p><input type="checkbox"/> In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.</p>
4.	<p>Additional comments:</p>

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Box No. II

Priority

1. ☒ The following document has not yet been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date in the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application
- ☒ claims Nos. 9 (industrial applicability)

because:

- ☒ the said international application, or the said claims Nos. 9 relate to the following subject matter which does not require an international preliminary examination (*specify*):

Claim 9 relates to subject matter which, in the opinion of this Authority, falls under PCT Rule 67.1(iv). Consequently, no expert opinion has been established in respect of the industrial applicability of the subject matter of said claims (PCT Article 34(4)(a)(i)).

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____ are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

- ☐ no international search report has been established for said claims Nos. _____

- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form

- ☐ has not been furnished
- ☐ does not comply with the standard

- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

- ☐ See Supplemental Box for further details.

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Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	1-9	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-9	NO
Industrial applicability (IA)	Claims	1-8	YES
	Claims		NO
2. Citations and explanations:			
1. Prior art			
<p>Substantive examination has been carried out with account taken of the following documents, cited in the search report:</p> <p style="margin-left: 40px;">D1: WO 03/041712 A (SMITH STEPHEN ALLAN; LIDDLE JOHN (GB); PINTO IVAN LEO (GB); FELL STEP) 22 May 2003 (2003-05-22)</p> <p style="margin-left: 40px;">D2: WO 00/66567 A (FENWICH ASHLEY EDWARD; SMITH STEPHEN ALLAN (GB); IFE ROBERT JOHN (GB)) 9 November 2000 (2000-11-09)</p>			
2. Novelty			
<p>Claims 1-9 meet the requirements of PCT Article 33(2): the compounds of the present claim 1 can be regarded as a novel selection over those from D1, owing to the 1,2,4-triazinone unit.</p> <p>The said 1,2,4-triazinone unit also represents the distinguishing feature in relation to the compounds from D2.</p>			
3. Inventive step			
<p>The present application, however, does not meet the requirements of PCT Article 33(3).</p>			

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Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
	<p>The problem of the present application can be seen as being that of providing further 1,2,4-triazinone derivatives suitable for the treatment of chronic-inflammatory diseases.</p> <p>The closest prior art is represented by D1. D1 discloses structurally similar compounds having qualitatively equivalent properties, from which the present compounds represent only a novel selection.</p> <p>Such a selection can only be regarded as being inventive if the selected compounds of the present application exhibit unexpected effects over the compounds from D1. However, no such effects have been described in the present application. In the absence of comparative data or other suitable information, it is not possible to assess whether this problem has been solved or not.</p> <p>With regard to the process claim there is no discernible inventive feature.</p> <p>Consequently, an inventive step cannot be acknowledged.</p>

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Box No. VI Certain documents cited

1. Certain published documents (Rule 43bis.1 and 70.10)

Application No.
Patent No.

Publication date
(day/month/year)

Filing date
(day/month/year)

Priority date (valid claim)
(day/month/year)

see supplemental sheet

2. Non-written disclosures (Rule 43bis.1 and 70.9)

Kind of non-written disclosure

Date of non-written disclosure
(day/month/year)

Date of written disclosure
referring to non-written disclosure
(day/month/year)

See form 210

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Box VI

Reference is made to the following document:

D3: WO 03/093268 A (ALONSO-ALIJA CRISTINA: BAYER AG (DE); BISCHOFF
HILMAR (DE); BURKHARDT) 13 November 2003 (2003-11-13)

D3 will be considered in any regional phase.